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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/690,083	10/20/2003	John Allen	LFS-5002	4870

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EXAMINER

SONNETT, KATHLEEN C

ART UNIT	PAPER NUMBER
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3731

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/17/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/690,083

Applicant(s)

ALLEN ET AL.

Examiner

Kathleen Sonnett

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 October 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

1. Applicant's arguments filed 10/17/2006 regarding the 102(e) rejections of claims 1-3, 6, and 8-11 over Roe et al. (U.S. 2004/0127818) have been fully considered but they are not persuasive. In particular, applicant argues that member (82) is driven toward the skin in a manner that flattens the skin and therefore does not anticipate a floating probe that is adapted to floatably contact the target site bulge as the bulge is created by the pressure tip. However, once actuator (44) has been rotated such that the floating probe (82) is not longer engaging thread (76) as seen in fig.4, the probe is floating with respect to piece (66) and is only engaging it because of biasing spring (94). That is, someone could reach inside of the device and pull the probe down since only spring (94) is biasing it toward the proximal end of the device. The probe can floatably make contact with the bulge because the probe can be moved independently of piece (66). Regarding the fact that the floating probe (86) of Roe et al. is used to flatten the top of the bulge, this is irrelevant because the overall bulge is still present due to the pressure tip (92) which creates the bulge (see fig. 2).

2. Applicant's arguments with respect to the 35 U.S.C. 102(b) of claims 1, 2, 4, 6-8, and 10-11 over Douglas et al. (U.S. 5,857,983) have been fully considered and are persuasive. The 35 U.S.C. 102(b) rejections of claims 1, 2, 4, 6-8, and 10-11 as being anticipated by Douglas et al. (U.S. 5,857,983), and the 35 U.S.C. 103(a) rejections of claim 3 over Douglas et al. in view of Roe et al. (U.S. 2004/0127818) and claim 5 over Douglas et al. in view of Böcker et al. (U.S. 5,997,561) have also been withdrawn.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. **Claims 1-3, 6, and 8-11** are rejected under 35 U.S.C. 102(e) as being anticipated by Roe et al. (U.S. 2004/0127818). Roe et al. discloses a lancing device comprising a lancet carriage (66), a lancet holder (50) slidably connected to the lancet carriage, a lancet (58) attached to the lancet holder, a floating probe (82) and a pressure tip (92). The floating probe is adapted to floatably contact the target site bulge and is configured to operatively interact with the lancet carriage to control penetration depth of the lancet into the bulge ([0070]). The lancet carriage and the floating probe are slidably connected to the housing and the lancing holder is slidably connected to the lancet carriage (see Fig. 4 and 5). The lancet is made of metal while the remaining elements of the lancing device are made of plastic, which is a rigid material ([0075]).
5. Regarding **claim 6**, the lancing device comprises a stop lock assembly (44, 60, [0070]).
6. Regarding **claim 8**, the pressure tip includes a probe stop surface (90) (see Fig. 1 and 5, [0066])
7. Regarding **claim 9**, the lancet carriage includes a lancet holder over-travel stop feature (74).

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8. Regarding **claims 10-11**, Roe et al. discloses the structure of the invention in claim 10 as stated above, and also discloses the method for lancing a target site. As seen in Fig. 3, the pressure tip contacts the target site, the pressure tip is urged toward the target site creating a bulge, and the target tissue is lanced while the floating probe operatively interacts with the lancet carriage to control a penetration of the lancet. The stop lock assembly (44, 60) locks the lancet carriage and floating probe in place so that the tissue is lanced with a predetermined penetration depth ([0068], [0070]).

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. **Claim 4** is rejected under 35 U.S.C. 103(a) as being unpatentable over Roe et al. in view of Douglas et al. Roe et al. disclose the invention substantially as stated above, including a decoupling spring (94). Roe et al. fail to disclose a launcher spring that is in series with the decoupling spring.

11. However, Douglas et al. disclose that it is old and well known in the art to include a spring system in series in a lancet system. The spring system disclosed by Douglas et al. controls the movement of the lancet holder with respect to the housing and trigger mechanism. A second spring in series with the decoupling spring (94) of Roe et al. could be added to control the movement of lancet holder (42) as it is not disclosed exactly how the position of the lancet holder is maintained when not depressed by the user. Therefore, it would have been obvious to one of ordinary skill in the art to modify the device disclosed by Roe et al. to include a launcher

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spring made obvious by Douglas et al. in order to provide a control for the positioning of the lancet holder relative to the lancet carriage.

12. **Claim 5** is rejected under 35 U.S.C. 103(a) as being unpatentable over Roe et al. in view of Böcker et al. (U.S. 5,997,561). Roe et al. discloses the invention substantially as stated above, but fails to disclose that the penetration depth is between 0.25mm and 1.5 mm.

However, Böcker et al. discloses that it is old and well known in the art to include a penetration depth of 0.25 mm to 1.5 mm in a lancing device that has a depth of penetration controlling means. Böcker et al. discloses that the penetration depth range can be set between 0.2 and 2.0 mm in order to provide about 100 microliters of body fluid. Therefore, it would have been obvious to one of ordinary skill in the art to modify the device disclosed by Roe et al. to include a penetration depth of between 0.25 mm and 1.5 mm made obvious by Böcker et al. in order to collect an appropriate amount of fluid for blood sampling.

13. **Claim 7** is rejected under 35 U.S.C. 103(a) as being unpatentable over Roe et al. in view of Levin et al. (U.S. 4,517,978). Roe et al. discloses the invention substantially as stated above including a floating probe spring (spring 94 now being considered floating probe spring), but fails to disclose an over-travel spring or launching spring that, along with the floating probe spring, are configured to control movement and positioning of the floating probe, lancet carriage, and lancet holder.

14. However, Levin et al. discloses that it is old and well known to include an over-travel spring (45) and launching spring (37) to control movement and position of a lancet carriage and holder (see col. 2 ll. 26-32; fig. 2). A similar series of springs could be added to the device of Roe et al. to control the movement of lancet holder (42) as it is not disclosed exactly how the position of the lancet holder is maintained when not depressed by the user or how it returns to its original position after actuation. Therefore, it would have been obvious to one of ordinary skill

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in the art to modify the device disclosed by Roe et al. to include an over-travel spring and launching spring as made obvious by Levin et al. in order to provide a control for the positioning and movement of the lancet holder and lancet carriage.


Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kathleen Sonnett whose telephone number is 571-272-5576. The examiner can normally be reached on 7:30-5:00, M-F, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anh Tuan Nguyen can be reached on 571-272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

KCS 1/4/2007


GLENN K. DAWSON
PRIMARY EXAMINER